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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,584	06/26/2003	Sho-Ya Wang	0794.047	8433
23405	7590	10/18/2004	EXAMINER	
HESLIN ROTHENBERG FARLEY & MESITI PC			CHANDRA, GYAN	
5 COLUMBIA CIRCLE			ART UNIT	PAPER NUMBER
ALBANY, NY 12203			1646	

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/608,584	WANG, SHO-YA
	Examiner Gyan Chandra	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 June 2004.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-45 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-45 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

## DETAILED ACTION

It is noted to Applicant that Claim 30 is interpreted by the Examiner to depend from Claim 28, rather than Claim 18 (as recited by the claims).

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claim 1-14, 31-45, drawn to a method of screen for assessing the potential of a compound to treat a pathological condition, classified in class 435, subclass 7.1.
2. Claims 23-27, 15-22, drawn to an isolated polynucleotide comprising a nucleotide sequence that encodes for a mammalian Nav protein, and a host cell, classified in class 435, subclass 69.1.
- 3-37. Claim 28, drawn to an isolated functional sodium channel protein comprising amino acid sequence of SEQ ID NO: 36-70, classified in class 530, subclass 300.
38. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO:36 + SEQ ID NO:60, classified in class 530, subclass 300.
39. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO:36 +SEQ ID NO:63, classified in class 530, subclass 300.
40. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO:36 + SEQ ID NO:66, classified in class 530, subclass 300.

41. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO:36 + SEQ ID NO:67, classified in class 530, subclass 300.
42. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO:36 + SEQ ID NO:68, classified in class 530, subclass 300.
43. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO:39 + SEQ ID NO:60, classified in class 530, subclass 300.
44. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 39 +SEQ ID NO: 63, classified in class 530, subclass 300.
45. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 39 + SEQ ID NO: 66, classified in class 530, subclass 300.
46. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 39 + SEQ ID NO: 67, classified in class 530, subclass 300.
47. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 39 + SEQ ID NO: 68, classified in class 530, subclass 300.
48. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO:42 + SEQ ID NO:60, classified in class 530, subclass 300.
49. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 42 +SEQ ID NO: 63, classified in class 530, subclass 300.
50. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 42 + SEQ ID NO: 66, classified in class 530, subclass 300.
51. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 42 + SEQ ID NO: 67, classified in class 530, subclass 300.

52. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 42 + SEQ ID NO: 68, classified in class 530, subclass 300.
53. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO:45 + SEQ ID NO:60, classified in class 530, subclass 300.
54. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 45 +SEQ ID NO: 63, classified in class 530, subclass 300.
55. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 45 + SEQ ID NO: 66, classified in class 530, subclass 300.
56. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 45 + SEQ ID NO: 67, classified in class 530, subclass 300.
57. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 45 + SEQ ID NO: 68, classified in class 530, subclass 300.
58. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO:59 + SEQ ID NO:60, classified in class 530, subclass 300.
59. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 59 +SEQ ID NO: 63, classified in class 530, subclass 300.
60. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 59 + SEQ ID NO: 66, classified in class 530, subclass 300.
61. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 59 + SEQ ID NO: 67, classified in class 530, subclass 300.
62. Claim 29, drawn to a functional sodium channel protein comprising SEQ ID NO: 59 + SEQ ID NO: 68, classified in class 530, subclass 300.

63-97. Claim 30, drawn to a functional sodium channel according to Claim 28 comprising a second amino acid of SEQ ID NO: 71, classified in class 530, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

Groups 2, and 3-97 are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

The polypeptides of group 3-97 and polynucleotide of group 2 are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group 2 does not necessarily encode a polypeptide of group 3-97. The information provided by the nucleic acids of group 2 can be used to make a materially different polypeptide than that of group 3-97. For example, a nucleic acid which hybridizes

to polynucleotide represented in Group 2, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with a polynucleotide of Group 2.

Searching the inventions of groups 2 and 3-97 together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups 2 and 3-97 have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene.

Searching, therefore is not coextensive.

Furthermore, searching the inventions of groups 3-97 together would impose a serious search burden. Each sequence requires a unique separate search of the prior art. Searching all of the sequences claimed in groups 3-97 would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches.

Inventions 2/3-97 and 1 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptide of Invention 3-97 could be used in diagnostic assays or to generate antibodies and polynucleotide of group 2 can be used in hybridization assay or gene therapy.

Searching the Inventions of Groups 2/3-97 and 1 together would impose a serious search burden. In the instant case, the search of the polypeptides, polynucleotides, and the method of using the polypeptides and polynucleotides are not coextensive. The inventions of Groups 2/3-97 and 1 also have a separate status in the art as shown by their different classifications.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement

between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571)272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra  
AU 1646  
26 September 2004

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